REMARKS

I. Introduction

Applicants gratefully acknowledge the courtesy extended to their undersigned attorney by Examiners Simmons and Steele during the personal interview on October 8, 2009. This response incorporates the substance of the interview, as required by MPEP § 713.05. Applicants now respectfully request reconsideration of the application in view of the remarks below.

II. Status of the Claims

No claims are cancelled or amended. Thus, claims 51-59 remain pending and are presented for reconsideration.

III. Response to the Office Action

The only concern in the Office Action is the PTO's maintained rejection of claims 51-59 under 35 U.S.C. § 103(a) for being allegedly unpatentable over Pathak, Benneker, and Chu. *See* Office Action at page 3. The Office Action and the Examiners during the interview asserted a number of bases for this rejection, none of which are factually or legally sound, for at least the reasons set forth below.

Pathak is cited for teaching paroxetine formulations with excipients such as calcium phosphate, sodium starch glycolate and magnesium stearate. As recognized by the PTO, Pathak does not teach or suggest the use of a sulfonate salt of paroxetine or calcium hydrogen phosphate anhydrate in the form of plate shaped crystals or agglomerates. Moreover, Pathak does not teach or suggest that the paroxetine formulations should have a pH of 5.0 to 6.0.

Benneker is cited for teaching sulfonate salts of paroxetine, and for teaching that such salts exhibit greater solubility, but Benneker does not teach or suggest the use of calcium hydrogen phosphate anhydrate in the form of plate shaped crystals or agglomerates, or paroxetine formulations with a pH of 5.0 to 6.0.

Chu is cited for teaching the use of calcium hydrogen phosphate anhydrate ("CHP") for direct compression tableting. Chu also is cited for its teachings regarding pH, as discussed in more detail below.

At page 3 of the Office Action, the PTO states that "a prima facie case of obviousness can be established when the claimed and prior art products are identical or substantially identical," and asserts that "[i]n this case, the prior art suggest a composition that is substantially identical to that which is claimed." Applicants respectfully disagree. The prior art does not teach or suggest any composition that is "the same" as those claimed. To the contrary, the PTO has made many selections and combined distinct teachings from three different references in an attempt to make out its case of obviousness. Moreover, its undertaking falls short for at least the reasons outlined herein.

Invoking a theory of inherency, the PTO's argument in chief is that the "prior art suggest[s] a composition that is substantially identical to that which is claimed . . ." and, hence, the prior art compositions would "reasonably be considered" to possess the claimed pH range. Office Action at page; 3*; see also* Interview Summary dated October 13, 2009. Further, the PTO asserted that because Chu teaches a pH of the ***medium*** in which calcium hydrogen phosphate ("CHP") can be prepared, then the claimed composition "is reasonably considered to maintain a similar – if not the same – pH when mixed with the active ingredients to form the tablet." Office Action at page 4. Even though no scientific theory supports this contention, the PTO nonetheless cited a purported teaching in Chu that adjusting pH of the ***reactions*** producing CHP can affect "the size and shape of [CHP] crystals," as identifying pH as a parameter suitable for optimizing "the compressibility of tablets containing [the] same." Office Action at 5. The errors in the PTO's position are explained below.

A. Chu Does Not Suggest a pH of a Composition that Contains Calcium Hydrogen Phosphate

Applicants' last response emphasized, as did their attorney during the interview, that the only pH discussed by Chu is that of a ***reaction medium*** from which its anhydrous dicalcium phosphate is ultimately isolated. *See* Chu at col. 1, line 64 to col. 2, line 8 and at

col. 3, lines 42-48. Chu does not disclose the pH of any resulting CHP product nor does the reference hint at a pH of a pharmaceutical composition that comprises the CHP product.

The PTO believes that a final product, *i.e.*, the claimed composition, is "reasonably considered" to possess a similar or the same pH when anhydrous dicalcium phosphate is mixed with the active ingredients. Office Action at page 4. Yet no rationale, scientific or otherwise, is provided in the PTO's commentary that remotely supports this belief, and nothing in the cited references supports such an assumption. To the contrary, as a matter of chemistry, the pH of a reaction medium in which anhydrous dicalcium phosphate is prepared and from which it is isolated is in no way correlated with the pH of the resultant CHP product, let alone the pH of a composition into which that product is incorporated as just one of several components.

Because Chu fails to teach or suggest a pH of its anhydrous dicalcium phosphate, the skilled artisan has no reasonable expectation that the CHP product will possess a given pH. Moreover, even if it is assumed, *arguendo*, that Chu does somehow suggest a pH of its CHP product, there still remains no reasonable expectation that a composition comprising Chu's CHP together with an active agent and other excipients would have a pH of 5.0 to 6.0, as recited in the instant claims.

B. The Cited Prior Art Does Not Suggest a Composition that Inherently Possesses a pH of 5.0 to 6.0

The pH of CHP is not fixed but instead varies according to its method of manufacture. Hence, a ***composition*** that comprises CHP does not necessarily possess the presently recited pH of 5.0 to 6.0. The PTO's reliance upon inherency in this context is therefore in error. To the extent that the PTO has showed "a sound basis for believing that the products of the applicant and the prior art are the same," *In re Spada*, 911 F.2d 705, 709 (Fed. Cir. 1990), a proposition that Applicants do not endorse for the reasons above, the present application sets forth countervailing evidence that rebuts any rejection based on inherency, by showing that any putative prior art composition does not "necessarily possess the characteristics of the claimed product." *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977).

As discussed during the interview, the application describes in some detail that commercially available CHP is "generally alkaline; i.e. pH ***greater than 7***. . ." Specification at 7 (emphasis added). A specific example is the product DI-TAB that has a pH of about 7.4. *Id.*

Despite this general trend of CHP having ***alkaline*** pH, which is higher than the range of 5.0 to 6.0 for the claimed ***composition***, some CHP gives rise to acidic or neutral pH. More specifically, the pH depends on the form and grade of CHP and whether and to what extent impurities remain in the CHP after processing. *Id.* at 7-8. The specification further elaborates upon specific commercial examples of CHP that possess pH of about or slightly below 7. Still, CHP is generally acknowledged to have a pH of about 7.3. *Id.* at 8.

Moreover, the specification teaches that pH ***of the composition*** can be governed by the use of a ***blend*** of CHP products, each having their different respective pH values. *Id.* In addition, ***excipients other than CHP*** can affect pH ***of the composition***. *Id.*

These teachings evidence that the pH of CHP varies from one product to another and depends upon a number of factors. That is to say, one cannot know *a priori* the pH of a given CHP. Because Chu does not teach the pH of its anhydrous dicalcium phosphate, there is no basis for the PTO's position that it falls within a certain range.

These teachings also show that there is no necessary correlation between the pH of the CHP used in a composition and the PH of the composition as a whole (comprising the CHP and other components), such as is presently claimed. This is especially true where, as here, components other than CHP can affect the pH of the composition. *See* specification at page 8.

Accordingly, the pH of the hypothetical composition pieced together by the PTO from the cited references cannot be said to possess a particular pH. Moreover, to the extent that the skilled artisan would assume that CHP has any specific pH value, it likely would be assumed to have a basic pH, as taught in the application for most CHP. Thus, there is absolutely no basis for the PTO's position that the teachings of Chu would be understood to directly or inherently suggest the pH of the claimed compositions.

In summary, because Chu does not teach or suggest the pH of its CHP, because the pH of CHP is not an inherent, characteristic of CHP but rather is variable, and because the pH of the CHP will not necessarily determine the pH of a composition comprising CHP and other ingredients, there really is no factual basis for the obviousness rejection. The rejection therefore is improper, and should be withdrawn.

C. Optimizing pH of a CHP Reaction Medium is Irrelevant to pH of the Claimed Composition

The PTO improperly discredited Applicants' earlier arguments showing that a skilled person would not be inclined to optimize the pH of the claimed composition because pH was not an art-recognized parameter to be varied or optimized. In short, the PTO stated that Chu does teach that pH is a parameter that can be optimized to affect size and shape of dicalcium phosphate crystals and, accordingly, affect the compressibility of tablets containing the same. *See* Office Action at page 5.

The PTO's comments miss the mark. Whether pH of a ***reaction medium*** can be adjusted to influence the size and shape of dicalcium phosphate crystals provides absolutely no reason to control the pH of a final ***composition*** comprising CHP, as claimed. The fact remains that the pH of CHP-containing compositions is a parameter that the cited art has ***not*** identified as one to be optimized. Thus, the principles of the precedential Board decision in *Ex parte Whalen II* discussed in Applicants' previous reply indeed are applicable here. "[T]he parameter optimized [the pH of the recited ***compositions***] was not recognized in the prior art as one that would affect the results," and so the doctrine of routine optimization does not apply. *Whalen II*, slip op. at 14. Moreover, there is no evidence of record that 'would support the conclusion that those skilled in the art would have considered it obvious to 'optimize' [the parameter at issue] . . . to the level recited in the claims," *Id.* Thus, the finding of obviousness is improper.

In summary, for the reasons of record, none of the cited references alone or in combination teach or suggest the claimed compositions. The references moreover fail to hint at the recited pH range of 5.0 to 6.0 for the claimed compositions. Further, because the references do not mention pH at all in connection with pharmaceutical compositions,

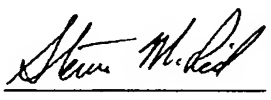
adjustment of pH of the composition is not an obvious modification that would yield the claimed compositions. Therefore, the person who is skilled in the art would not consider the compositions to be obvious, nor would he be led to them by the teachings of the cited references. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

For all of these reasons, the claimed composition is patentable over Pathak, Benneker, and Chu. Accordingly, the PTO should reconsider and withdraw the rejection.

CONCLUSION

Having advanced credible grounds for the withdrawal of the only rejection, Applicants believe that the application is in condition for allowance. Accordingly, Applicants respectfully request favorable reconsideration of the application. If Examiner Simmons believes that any outstanding issue warrants discussion, he is courteously invited to contact by telephone Applicants' undersigned attorney at the number below.

Respectfully submitted,

By 

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The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.